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REMARKS

Claims 1-4, 6-17, and 19-31 are pending. Claims 1, 8, 12, 27, and 30 have been amended. Claims 32 and 33 have been added. Support for the amendments and new claims is found in the Specification as filed at least on page 4, paragraph 14; page 9, paragraphs 33 and 34; page 10, paragraph 43; page 12, paragraph 53; and FIGS. 1 and 3. No new matter has been added. The rejections of the claims are respectfully traversed in light of the amendments and following remarks, and reconsideration is requested.

Premature Final Office Action

Applicant cannot find any consideration by the Examiner on the merits of Applicant's earlier amendment inserting "an intra-abdominal ultrasound device" in Claim 27 (made in the Response to Office Action dated September 4, 2003), and submits that the present Final Office Action is premature. MPEP §707.07 (e) and (f) requires that "[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it."

The present invention has been made possible by the addition of several technical advances to laparoscopy including intra-abdominal ultrasound. Intra-abdominal ultrasound has resulted in the ability to detect and target tumors not previously visible with laparoscopy (i.e., looking inside the abdomen with a "scope"). This in turn resulted in the ability to treat tumors regardless of location, size, and/or number. Applicant submits that intra-abdominal ultrasound has not been applied to gynecologic conditions as claimed by Applicant. See Dr. Lee Affidavit, paragraph 13, attached hereto as Attachment A. Accordingly, Applicant requests reconsideration and withdrawal of the finality of the present Office Action.

Even if such withdrawal is not forthcoming, Applicant makes the following remarks and requests reconsideration.

Applicant respectfully submits that the claims as amended are patentable over the references of record, specifically Savage et al. (U.S. Patent No. 5,979,453 hereinafter "Savage"), Behl (U.S. Patent No. 6,212,433), Edwards et al. (U.S. Patent No. 5,935,123 hereinafter "Edwards"), Burbank et al. (U.S. Patent No. 6,254,601 hereinafter "Burbank"), Schmaltz et al. (U.S. Patent No. 6,190,383 hereinafter "Schmaltz"), and Moorman et al. (U.S. Patent No. 6,355,033 hereinafter "Moorman"), alone or in combination.

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Rejections Under 35 U.S.C. § 103(a)
Savage in view of Behl and further in view of Edwards

Claims 1, 2, 6-13, 16, 19-23, and 25-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards. In rejecting the claims, the Examiner writes in part:

Savage . . . neglects to disclose insertion of the ablation device directly into the tumor and a plurality of deployable arms.

Behl discloses a tumor ablation device (20; fig. 2) that is inserted into a tumor (T) as illustrated in figure 6c. Moreover, Behl discloses a plurality of deployable (from the tip of the ablation device) electrode arms (32; figures 3 & 6c; column 10 lines 21-24.)

...
Savage and Behl, neglect to disclose complete insertion of the electrodes into the targeted tumor.

Edwards . . . discloses an analogous tumor treatment system and method in which the device electrode is inserted completely within the targeted tumor (154) as depicted in figure 15.

...
[I]t would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards by including a plurality of deployable electrode arms as a design expedient as well as complete insertion of the device electrode into the targeted tumor. The motivation would be to uniformly generate heat throughout a desired target tissue volume through the use of symmetrically spaced apart electrodes as disclosed in Behl column 1 lines 36-39. The nexus between Savage and Behl is found in Behl col. 4:20-24 and 37-47. Behl's "two-step method" in col. 4:43-44 includes as a first step targeting blood flow to the targeted tumor prior to targeting the tumor itself. This first step is analogous to Savage's disclosed protocol. The motivation for complete insertion of the electrode into the targeted tumor would be to minimize damage of healthy peripheral tissue due to the heat generated by the electrode.

The Examiner Has Improperly Combined the References Using Hindsight

Applicant respectfully submits that the Examiner has used hindsight to combine selected references in the combination taught by Applicant. Such use of hindsight is improper. As stated by the Federal Circuit:

"One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *on remand*, 13 U.S.P.Q.2d 1192 (D. Conn. 1989).

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Finding obviousness through hindsight (i.e., after the fact of the invention and with the teachings of the inventor available) is impermissible and refuted by the objective indicia of nonobviousness. Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999); In re Piasecki, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984); In re Sernaker, 702 F.2d 989, 217 U.S.P.Q. 1 (Fed. Cir. 1983).

Applicant submits that this is exactly what the Examiner has done here and that the Examiner's obviousness rejection is improper as based not only on hindsight (*see* Chisum, Section 5.03[2][c]) but also on the fallacious assumption that Applicant's claimed method involving placing "three or more electrodes deployable from the tip" of an ablation device is obvious in view of references which teach either a single electrode being placed in a tumor or bipolar electrodes being placed in a tumor. Such an assumption is without support in the references cited by the Examiner and not supported in the art because of the significant difference in ablation volume and shape between one or two needles (as taught in the cited references), and three or more electrodes deployable from a tip of an ablation device (as claimed in the present invention).

Ablation of the tumor mass itself with a prior art monopolar or bipolar needle system has inherent difficulties. Since the shape of the ablation zone with prior mono or bipolar systems is oval, cylindrical, or planar, and since fibroids are most often spherical, effective ablation of fibroids requires multiple and possibly numerous passes. This results in significant destruction of surrounding tissue and is time consuming. See Dr. Lee Affidavit, paragraph 6, attached hereto as Attachment A.

Prior method not optimal
6/6

In contrast, the ablation device used in the present invention is capable of entering and ablating a defined area of variable and predictable size with appropriate ablation volume/shape for treating fibroids. See Dr. Lee Affidavit, paragraph 11, attached hereto as Attachment A.

The References Are Not Properly Combinable
Because They Do Not Suggest a Motivation to Combine

Applicant further submits that the references do not teach or suggest the combination. As stated by the Federal Circuit:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1318 (fed. Cir. 2000); *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); MPEP § 2143.01.

The Examiner writes in part that the "motivation [to modify Savage in view of Behl and further in view of Edwards to include a plurality of deployable electrode arms] would be to uniformly generate heat throughout a desired target tissue volume through the use of symmetrically spaced apart electrodes" and as a "design expedient." However, Savage only discloses "electrosurgical needles, needle systems, and methods for their use which will allow the surgeon to target a tumor's blood supply." (Savage, col.2, ll.22-24). Savage further discloses a "needle system 40" including a "Doppler ultrasound image system 46" to provide "an image of bloodflow." (Savage, col.5, ll.38-44, emphasis added). Savage discloses that "if bipolar current is to be used, a pair of needles may be extended rather than a single needle." Regardless, this technique could reduce the number of passes required for definitive tumor reduction therapy, thereby reducing operating time and the risk of adhesion formation." (Savage, col.4, ll.52-57).

Thus, Savage discloses no motivation to use more than a pair of needles to target the blood supply and instead teaches away because using more than a plurality of needles would reduce the precision of the needle system and method as taught by Savage while causing more damage to surrounding healthy tissue (see Dr. Lee Affidavit, paragraph 22, attached hereto as Attachment A), and Savage expressly teaches that damage to the normal surrounding muscle and tissue is to be reduced. For example, Savage expressly teaches:

[T]he present invention will reduce damage to the serosa (Savage, col.2, ll.32-34).

Ideally, the temperature sensor is coupled to the ESU through a temperature control system 50, so as to provide the necessary coagulation with minimal trauma, such as injury to the uterine serosa, adhesion formation, and the like. (Savage, col.6, ll.2-6).

Accordingly, the Savage and Behl references do not disclose or suggest the desirability of the combinations or modifications suggested by the Examiner. Instead, combining the teachings of Savage with the plurality of electrodes as disclosed in Behl would destroy the intent and purpose of Savage to use a needle system and method to target a tumor's blood supply with reduced damage to the normal healthy tissue surrounding the tumor. See Dr. Lee Affidavit, paragraph 26, attached hereto as Attachment A.

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*Savage
teaches
away from
plurality
of needles*

The Examiner further writes in part that the "motivation for complete insertion of the electrode into the targeted tumor would be to minimize damage of healthy peripheral tissue due to the heat generated by the electrode." However, both Savage and Behl explicitly disclose the desirability of placing electrodes outside of the targeted tumor. See e.g., Savage, FIG.3; Behl, FIG. 6A-7.

incorrect, Behl places electrode in tumor fig 6

Accordingly, the Savage and Behl references do not disclose or suggest the desirability of the combinations suggested by the Examiner. Combining Edwards with Savage and Behl would destroy the intent and purpose of Savage and Behl to target a tumor's blood supply. See Dr. Lee Affidavit, paragraph 28, attached hereto as Attachment A.

The References Are Not Properly Combinable
Because Their Intended Function is Destroyed and the References Teach Away

Applicant further submits that Edwards is not properly combinable with Savage and Behl (assuming these references were combined) because Savage and Behl teach away from complete insertion of an electrode within a tumor.

Savage discloses that "it would be desirable to provide improved needle myolysis systems and methods to facilitate the accurate, controlled targeting of a tumor's blood supply." (Savage, col.2, ll.13-16). Savage further discloses that "tumor shrinkage can be preferentially induced by destroying the tumor's blood supply, which is generally located on the periphery, rather than by targeting the bulk of the fibroid. Physicians . . . use the needles to ring the tumor with cores of coagulation. This technique still calls for multiple tumor passes and, in the end, the operator remains uncertain as to the status of the tumor's blood supply." (Savage, col.1, ll.43-50). Such a procedure causes damage to the normal surrounding muscle and tissue. See Dr. Lee Affidavit, paragraph 22, attached hereto as Attachment A. Savage then explicitly discloses that "the [Savage] sheath transducer permits the surgeon to target the blood supply of a fibroid, prostatic adenoma, or other tumor by placing the end of the sheath against adjacent tissues." (Savage, col.4, ll.32-35). Thus, Savage discloses heating tissue adjacent a tumor to target the blood supply of a tumor and not the bulk of the tumor itself. Accordingly, Savage teaches away from insertion of an electrode completely within the tumor.

*Savage says **

Behl does not remedy the deficiencies of Savage noted above. Behl teaches the application of "electrical energy, such as radio frequency or other high frequency energy, to or between an internal tissue site and an external tissue site on the surface of the organ." (Behl, col.2, ll.44-48). Thus, by placing an electrode external to the tumor, Behl teaches away from

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Applicant's claimed invention of "deploying the plurality of electrodes within a pelvic tumor to avoid contact with normal tissue outside of the pelvic tumor." See Claim 1, lines 4-5; Claim 12, lines 10-11, Claim 30, lines 5-6, and Claim 33, lines 6-7. As noted by the Examiner, Behl discloses a step to "first necrose tissue at or near a distal periphery of the target region so that the vasculature is at least partly destroyed in order to reduce the blood flow into . . . the target region." (Behl, col.4, ll.39-42). Behl further discloses that the electrode array is "powered first in order to necrose tissue at a boundary of the target region and inhibit blood flow into the region." (Behl, col.8, ll.54-56). As shown in FIG. 6C, Behl discloses that deployed electrodes 32 are placed in tissue adjacent the tumor to necrose a boundary region B1 and thereby inhibit blood flow. Normal tissue outside of the tumor is not avoided. (Behl, col.11, ll.11-14; FIG. 6A-6C). Thus, even if Savage were modified by Behl, such a combination still targets the blood supply of a tumor by heating tissue adjacent a tumor with a plurality of electrodes. Accordingly, Savage in view of Behl still teaches away from insertion of the electrodes completely within the tumor. See Dr. Lee Affidavit, paragraph 27, attached hereto as Attachment A.

Edwards is not properly combinable with Savage and Behl (assuming arguendo that Savage and Behl are combinable) because such a combination destroys the intent, purpose, and function of Savage and Behl to target the blood supply of the tumor, which requires heating of tissue adjacent the tumor as taught in Savage and Behl. Edwards does not disclose or suggest targeting a tumor's blood supply or a peripheral area adjacent the tumor to target the blood supply. Instead, Edwards discloses a single electrode for targeting the bulk of the tumor itself. Thus, Savage modified in view of Behl is not properly combinable with Edwards to show insertion of electrodes completely within the tumor because such a combination would destroy the purpose and function of Savage and Behl to target the tumor's blood supply by ablating the periphery of a tumor. See Dr. Lee Affidavit, paragraph 28, attached hereto as Attachment A.

Even If Savage and Behl and Edwards Were Combined,
They Do Not Disclose or Suggest All Limitations

Even if the references were combined, Applicant submits that Savage in view of Behl and further in view of Edwards does not disclose or suggest all the limitations of Claims 1 and 12. In particular, Applicant could not find any disclosure or suggestion in Savage, Behl, and Edwards, alone or in combination, of the novel use of an intra-abdominal ultrasound probe separate from the ablation device in combination with all the other elements of Claims 1 and 12.

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The Present Invention

In contrast, Claims 1 and 12 recite "deploying the three or more electrodes within a pelvic tumor to avoid contact with normal tissue outside of the pelvic tumor" and "confirming placement of the three or more electrodes completely within the pelvic tumor with . . . laparoscope and . . . imaging device including an intra-abdominal ultrasound probe." Therefore, because Behl is not properly combinable with Savage, because Edwards is not properly combinable with Savage and Behl, and because Savage, Behl, and Edwards do not disclose or suggest all the limitations of Claims 1 and 12 even if the references were combined, Claims 1 and 12 are patentable over Savage in view of Behl and further in view of Edwards.

Claims 2 and 6-11 are dependent on Claim 1 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 2 and 6-11 are allowable for at least the same reasons provided above for Claim 1.

Claims 13, 16, 19-23, and 25-26 are dependent on Claim 12 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 13, 16, 19-23, and 25-26 are allowable for at least the same reasons provided above for Claim 12.

Savage, Behl, Edwards, Burbank, Schmaltz, and Moorman, alone or in combination, also fail to disclose or suggest a system including "an ablation device for insertion into a pelvic region of a patient, wherein the ablation device includes a tip and three or more electrodes deployable from the tip; . . . a laparoscope for insertion of the plurality of electrodes within a pelvic tumor of the patient to avoid contact with normal tissue outside of the pelvic tumor; and an intra-abdominal ultrasound probe separate from the ablation device for observing a location of the three or more electrodes completely within the pelvic tumor of the patient, wherein the laparoscope and the intra-abdominal ultrasound device are connected to at least one monitor, the at least one monitor being located along a first side of an operating table, and wherein the energy source and the intra-abdominal ultrasound device are located adjacent the at least one monitor along the first side of the operating table," as recited in Claim 27. Applicant is not aware of such a combination of elements having been utilized in gynecology or surgery in the pelvic area. Such a combination allows for the accurate ablation of smaller tumors and accordingly more comprehensive ablation of tumors without damage to surrounding healthy tissue. See Dr. Lee Affidavit, paragraphs 13 and 14, attached hereto as Attachment A.

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Claims 28-29 are dependent on Claim 27 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 28-29 are allowable for at least the same reasons provided above for Claim 27.

Claim 30 recites "inserting a tip of an ablation device including three or more electrodes deployable from the tip into a single puncture site in a pelvic region, the puncture site being approximately 1 mm to 2 mm in diameter; deploying the three or more electrodes within at least one pelvic tumor to avoid contact with normal tissue outside of the at least one pelvic tumor, the at least one pelvic tumor having a diameter of at least 1 cm; confirming placement of the three or more electrodes completely within the at least one pelvic tumor with a laparoscope and an imaging device including an intra-abdominal ultrasound probe; delivering RF energy to the ablation device; and heating the at least one pelvic tumor to a temperature between approximately 85 °C and approximately 100 °C for between approximately 7 and 14 minutes, wherein from the single puncture site substantially all of the at least one pelvic tumor is ablated."

The present invention advantageously allows for comprehensive ablation of a tumor area with only a single puncture as opposed to bipolar methods ablating tissue between two separate needles. A device including two separate needles for bipolar mode ablation disadvantageously causes multiple punctures upon entering the organ to be treated and only ablates tissue between the needles, thus usually requiring multiple passes for ablation of the entire tumor area. Savage in view of Behl and further in view of Edwards disadvantageously disclose multiple punctures and/or passes for shrinking a tumor. Accordingly, because Edwards is not properly combinable with Savage and Behl and even if combined, the references do not disclose all the limitations of Claim 30, Claim 30 is patentable over Savage in view of Behl and further in view of Edwards.

Claim 31 is dependent on Claim 30 and contains additional limitations that further distinguish it from Savage in view of Behl and further in view of Edwards. Therefore, Claim 31 is allowable for at least the same reasons provided above for Claim 30.

Rejections Under 35 U.S.C. § 103(a)

Savage in view of Behl and further in view of Edwards and further in view of Burbank

Claims 3, 4 and 14-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank.

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Burbank discloses devices and methods "for treating a uterine disorder which receive its blood supply from a uterine artery. In particular, uterine fibroids are effectively treated by occluding the uterine arteries." (Burbank, Abstract). Thus, Burbank only discloses targeting a uterine artery as a blood supply to the uterine itself and does not disclose or suggest ablating the fibroid itself. Accordingly, Burbank does not remedy the deficiencies of Savage, Behl, and Edwards noted above with regard to Claims 1 and 12. Claims 3-4 and 14-15 are dependent on Claims 1 and 12, respectively, and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards and further in view of Burbank. Therefore, Claims 3-4 and 14-15 are allowable for at least the same reasons provided above for Claims 1 and 12, respectively.

Rejections Under 35 U.S.C. § 103(a)
Savage in view of Behl and further in view of Edwards and
further in view of Burbank and further in view of Schmaltz

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank and further in view of Schmaltz.

Schmaltz discloses needle electrodes which "are mounted for rotation to facilitate entry and passage through tissue." (Schmaltz, col.3, ll.3-5). Schmaltz, in combination with Savage, Behl, Edwards, and Burbank, does not disclose or suggest "deploying the three or more electrodes within a pelvic tumor to avoid contact with normal tissue outside of the pelvic tumor" and "confirming placement of the three or more electrodes completely within the pelvic tumor with . . . laparoscope and . . . imaging device including an intra-abdominal ultrasound probe separate from the ablation device," as recited in Claim 12. Accordingly, Schmaltz does not remedy the deficiencies of Savage in view of Behl and further in view of Edwards and further in view of Burbank noted above with regard to Claim 12. Claim 17 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Behl and further in view of Edwards and further in view of Burbank and further in view of Schmaltz. Therefore, Claim 17 is allowable for at least the same reasons provided above for Claim 12.

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Rejections Under 35 U.S.C. § 103(a)Savage in view of Behl and further in view of Edwards and further in view of Moorman

Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Moorman.

Moorman discloses a "modular biopsy and microwave ablation needle and delivery apparatus adapted for in situ assembly." (Moorman, col.2, ll.55-57). Moorman, in combination with Savage, Behl, and Edwards, does not disclose or suggest "deploying the three or more electrodes within a pelvic tumor to avoid contact with normal tissue outside of the pelvic tumor" and "confirming placement of the three or more electrodes completely within the pelvic tumor with . . . laparoscope and . . . imaging device including an intra-abdominal ultrasound probe separate from the ablation device," as recited in Claim 12. Accordingly, Moorman does not remedy the deficiencies of Savage, Behl, and Edwards noted above with regard to Claim 12. Claim 24 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Behl and further in view of Edwards and further in view of Moorman. Therefore, Claim 24 is allowable for at least the same reasons provided above for Claim 12.

New Claims

Claims 32 and 33 have been added. Claim 32 is dependent on Claim 30 and contains additional limitations that further distinguish it from Savage, Behl, Edwards, Burbank, Schmaltz, and Moorman, alone or in combination. In particular, Claim 32 recites "repositioning the ablation device proximate a second pelvic tumor from the single puncture site." Applicant submits that the cited references do not disclose or suggest ablation of a plurality of tumors from a single puncture site. Therefore, Claim 32 is allowable for at least the same reasons provided above for Claim 30.

Applicant submits that the references of record, including Savage, Behl, Edwards, Burbank, Schmaltz, and Moorman, alone or in combination, do not disclose or suggest "manipulating a uterus with an intra-abdominal ultrasound probe to position and stabilize the uterus, wherein the uterus has at least one uterine fibroid", "deploying the at least three electrodes within the uterine fibroid to avoid contact with normal tissue outside of the uterine fibroid", and "confirming placement of the at least three electrodes completely within the uterine fibroid with a laparoscope and the intra-abdominal ultrasound probe," as recited in Claim 33.

The ultrasound transducer disclosed in Savage cannot be used to manipulate a bodily organ so as to position and stabilize the organ while the needle is being inserted because the ultrasound transducer is directly connected to the distal end of the needle. (Savage, col.3, ll.62-65, FIG. 1). *See also* Dr. Lee Affidavit, paragraph 23, attached hereto as Attachment A.

Accordingly, because the references of record, alone or in combination, do not disclose all the limitations of Claim 33, Claim 33 is patentable over Savage, Behl, Edwards, Burbank, Schmaltz, and Moorman, alone or in combination.

Rebuttal to Examiner's Response to Amendments

In responding to prior amendments, the Examiner writes in part:

Applicant's [prior] amendments to claims 1-4, 6-17, and 19-30 have been considered.

Applicant's arguments filed 9-14-03 have been fully considered but they are not persuasive. The Applicant claims that the combination of Edwards et al. to Savage and Behl would destroy the intended function of Savage and Behl. This might be true (insertion of electrodes for ablating into a tumor is not equivalent to placing electrodes adjacent a tumor to treat blood supply) in a vacuum. However, one must consider the context in which the prior art and the application are found. Both groups involve ablative treatment of a tumor. Generally, this means that energy is applied to the body with the purpose of shrinking/destroying a tumor. Surgeons are fully aware of different techniques (ex. placement of electrodes) to shrink tumors with ablative energy and can take the approach that "there is more than one way to skin a cat." Insertion of electrodes into a tumor or adjacent a tumor for the purposes of destroying that tumor are simply too close as techniques/protocols/methods to claim that one is not obvious in light of the other. To this end, the Examiner respectfully submits that the combination of the prior art is valid, and in the contexts in which the methods are found (destroying a tumor), are seamlessly combinable, especially to a medical professional who often undertakes these types of surgeries.

Applicant submits that ablation of a tumor by insertion of electrodes into a tumor mass and ablation of a tumor by insertion of electrodes into adjacent tissue in order to attack blood supply are highly different procedures albeit with the same goal of treating tumors. *See* Dr. Lee Affidavit, paragraphs 5-9, attached hereto as Attachment A.

As disclosed by Schmaltz, "sticking the electrodes into a myoma may cause trauma to the uterus upon penetration attempts into the myoma. This is particularly true in the single or dual bipolar needle devices which require multiple penetrations into tissue for complete

ablation.” (Schmaltz, col.2, ll.10-16). Schmaltz further discloses that one doctor reports that “an average of thirty to fifty passes into different areas of a myoma with the bipolar needle is required in order to achieve complete tissue necrosis.” (Schmaltz, col.2, ll.18-23).

Quite differently, Savage discloses that “[r]ecently, Goldrath and others have demonstrated that tumor shrinkage can be preferentially induced by destroying the tumor’s blood supply, which is generally located on the periphery, rather than by targeting the bulk of the fibroid.” (Savage, col.1, ll.43-46) (emphasis added). Savage further discloses that “[p]hysicians acting on this observation use the needles to ring the tumor with cores of coagulation. This technique still calls for multiple tumor passes and, in the end, the operator remains uncertain as to the status of the tumor’s blood supply.” (Savage, col.1, ll.47-51).

At least as shown by the references of record, in particular Schmaltz and Savage, targeting the tumor mass itself and targeting the tumor’s blood supply are highly different methods. *See also* Dr. Lee Affidavit, paragraphs 5-9, attached hereto as Attachment A.

Thus, Applicant submits that although direct ablation of a tumor itself and indirect tumor treatment via ablation of a tumor’s blood supply have the same desirable goal to treat the tumor, they are quite different methods in view of each other to one of ordinary skill in the art at the time of the present invention. *See* Dr. Lee Affidavit, paragraph 5-9, attached hereto as Attachment A. Accordingly, Edwards is not properly combinable with Savage and Behl.

The present invention advantageously treats essentially only the tumor itself, is not traumatic to the normal surrounding muscle, causes minimal damage to the serosa, and brings about resolution of symptoms and return to normal activity in about 95% of cases. Prior methods and systems have caused uterine rupture and other complications. *See* Dr. Lee Affidavit, paragraphs 9 and 10, attached hereto as Attachment A.

Under Graham v. John Deere, 383 U.S. 1, 48 U.S.P.Q. 459 (1966), commercial success and acquiescence by the industry through negotiation of licensing-type agreements are evidence of non-obviousness. Applicant’s procedure has met with commercial success. Furthermore, a development agreement has been negotiated for rights to the present invention between Rita Medical Systems, Inc., assignee of the Edwards patent, and BEKL Corporation, assignee of the present Application. Furthermore, the Applicant is currently in negotiations with two other medical device companies. *See* Dr. Lee Affidavit, paragraphs 16 and 17, attached hereto as Attachment A.

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Applicant submits that the commercial success and acquiescence by the industry enjoyed by Applicant is an indication that the combination of elements in the ablation method and system of the present invention is nonobvious and should have relevancy as indicia of nonobviousness of the present invention.

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CONCLUSION

For the foregoing reasons, Applicant believes pending Claims 1-4, 6-17, 19-27, and 29-33 are allowable, and a notice of allowance is respectfully requested. If the Examiner has any questions or concerns, the Examiner is hereby requested to telephone Applicant's Attorney at (949) 752-7040.

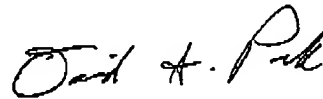
Certification of Facsimile Transmission

I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.


Sandy Kim

February 17, 2004
Date of Signature

Respectfully submitted,



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